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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,715	04/30/2001	George Jackowski	2132.030	3820
21917	7590	12/14/2006	EXAMINER	
MCHALE & SLAVIN, P.A. 2855 PGA BLVD PALM BEACH GARDENS, FL 33410			SKIBINSKY, ANNA	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/845,715

Applicant(s)

JACKOWSKI ET AL.

Examiner

Anna Skibinsky

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 36-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 is/are allowed.
- 6) ☐ Claim(s) 36-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Amendment to the Claims

Amendment to claims 36 are acknowledged. Claims 1 and 36-43 are under examination.

Claim Rejections - 35 USC § 112, 1st Paragraph

The rejection of claim(s) 41-43 for New Matter under 35 USC § 112-1st paragraph in the Office Action filed 1/03/06 is withdrawn in view of Applicant's Remarks/Amendments filed 3/30/06.

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 36-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

3. In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation." These factors include: (a) the

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quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) In order to use the claimed invention one of skill in the art must identify a specific amino acid sequence from a mass spectrometry peak that relates only the mass to charge ratio. For the reasons discussed below, there would be an unpredictable amount of experimentation required to practice the claimed invention.

b) The description does not provide detailed guidance as to how to confirm a specific amino acid sequence with a mass spectrometry peak that only provides mass to charge ration information.

c) The description does not provide working examples of confirming a specific amino acid sequence from a mass spectrometry peak.

d) The nature of the invention, of confirming a specific polypeptide sequence required knowledge of the specific ordering of amino acids in the sequence.

e) The prior art shows that mass spectrometry can give information of the mass to charge ratio of polypeptide fragments, however, determining the exact sequence from a single mass spectrometry peak is not taught.

f) The skill of those in the art of polypeptide sequence characterization is high.

g) The predictability of the relationship of connection of the location of a single mass spectrometry peak (i.e. the polypeptide mass) to the exact sequence that confirms

a specific polypeptide is unknown in the prior art.

h) The claims is broad in that it does not specify how an exact polypeptide sequence can be confirmed from only a single mass spectrometry peak.

The skilled practitioner would first turn to the instant description for guidance in using the claimed invention. However, the description lacks clear evidence that a specific sequence of amino acids in a particular order can be determined from a single mass spectrometry peak. As such, the skilled practitioner would turn to the prior art for such guidance, however the prior art does not discuss the determination of amino acid arrangements from one mass spectrometry peak. Finally, said practitioner would turn to trial and error experimentation to confirm the polypeptide sequence claimed. Such amounts to undue experimentation.

4. Claim 36(c) recites "confirming the presence of ... amino acid residues 2-12 of SEQ ID NO:1 in said sample by identifying a mass spectral profile having an ion peak at about 1348 daltons...". The mass spectrometry peak at 1348 (or about 1348) is used to confirm the presence of the specific polypeptide with the sequence disclosed and described on page 31, lines 13-16 of the specification. However, the use of the mass spectrometry peak at "about 1348 daltons" for the confirming of said sequence is not enabled because a sequence with same amino acids but in a different order of arrangement would also be detected at 1348 daltons. Additionally a similar amino acid sequence with slight modifications could also potentially have a mass of "about 1348" daltons. Therefore, the identification of the peak does not confirm the presence of the claimed sequence in the sample.

REPLY TO APPLICANTS

5. Applicant's arguments filed 9/18/2006 have been fully considered but they are not persuasive.
6. Applicant's argue that diagnosis of myocardial infarction, intracerebral hemorrhage, or congestive heart failure is made if the mass spectral profile as shown in Figure 2 is found in a mass spectral profile obtained from an unknown sample when the claimed (amino acid residues 1-12 of SEQ ID NO:1) is determined to be present in the sample and the patient from which the sample was obtained is diagnosed with myocardial infarction, intracerebral hemorrhage, or congestive heart failure (Remarks, page 11, lines 10-18).
7. In response to applicant's argument, it is noted that the features upon which applicant relies (i.e., see Remarks, page 11, lines 10-18) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Claim 36 recites that the identification of a peak at 1348 daltons with mass spectrometry confirms the presence of a biopolymer marker with consisting of amino acid residues 2-12 or SEQ ID NO.: 1 and diagnoses myocardial infarction, intracerebral hemorrhage, or congestive heart failure (claim 36, part (c)).
8. The claim does not recite any previous or additional diagnosis of the patient as argued by Applicant (Remarks, page 11, lines 16-18) which is needed to diagnose the patient using the identification of the marker.

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9. Furthermore, mass spectrometry alone is not sufficient to determine the absolute presence of the recited sequence. The specification recites further tests to discern the presence of the sequence (Specification, page 26, line 20 to page 27, line 2). The presence of each marker specific to the disease is also tested (Specification, page 28, lines 17-20).

Allowable Subject Matter

10. Claim 1 is allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anna Skibinsky whose telephone number is (571) 272-4373. The examiner can normally be reached on 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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